





Attorney Docket No.: 7640-X06-058

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:

Avidor SHULMAN et al

Confirmation No.: 9066

Serial No:

10/576,239

Group Art Unit: 1761

Filed:

April 18, 2006

Title:

A LIPID PREPARATION FOR ENHANCING MINERAL

ABSORPTION

CERTIFICATE OF EXPRESS MAILING

PATENTS

EXPRESS "Express Mail" Mailing Label number EV 820314257 US Date of Deposit December 15, 2006

I hereby certify that the attached paper(s) or fee(s) is/are being deposited with the United States Postal Services "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to the Commissioner of Patents, P. O. Box 1450 Alexandria, VA 22313-1450.

(Signature of person mailing paper or fee)

ESTEFANIA BELAUNDE

(Typed or printed name of person mailing paper or fee)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Avidor SHULMAN et al Confirmation No.: 9066

Application No.: 10/576,239 Attorney Docket No.: 7640-X06-058

Filed: April 18, 2006 Group Art Unit: 1761

For: A LIPID PREPARATION FOR ENHANCING MINERAL ABSORPTION

INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. § 1.56

Commissioner for Patents Alexandria, VA 22313

Sir:

In accordance with the duty of disclosure provisions of C.F.R. § 1.56, there is hereby provided certain information, which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

A revised Form PTO/SB/08a and PTO/SB/08b listing all patents, publications, applications, or other information submitted for consideration is enclosed.

As some of the references were cited in the International Search Report (ISR) for the corresponding PCT application, a copy of the ISR is also enclosed.

No admission is made that the information cited in this Statement is, or is considered to be prior art, material to patentability nor a representation that a search has been made.

This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b) before the latter of three months after the U.S. patent application filing date or the first Office Action on the merits. Accordingly, no fee or certification is required.

Respectfully submitted,

Dated: 15 Dec 2006

Paul D. Bianco (Reg. No. 43,500)

Attorney for Applicant

Fleit Kain Gibbons Gutman Bongini & Bianco P.L.

21355 East Dixie Highway

Suite 115

Miami, Florida 33180

305-830-2600 (telephone)

PTO/SB/08A (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

Complete if Known

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Examiner Name

Substitute for form 1449/PTO

Application Number 10/576,239 April 18, 2006 Filing Date First Named Inventor Avidor SHULMAN Art Unit 1761

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

7640-X06-058 Attorney Docket Number Sheet 1

			U. S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ^{2 (f known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	^{US-} 3,542,560	11-24-1970	Tomarelli et al	
	AB	^{US-} 4,876,107	10-24-1989	King et al	
	AC	^{US-} 5,658,768	08-19-1997	Quinlan	
	AD	^{US-} 5,709,888	01-20-1998	Gil et al	
		US-			
		US-		·	
		US-			
		US-			
		US-			
	 	US-			
		US-			
	 	US-			

		FORE	IGN PATENT DOCL	JMENTS			
Examiner Initials*	Cite No.1		Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	_
		Country Code ³ "Number ⁴ "Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T⁵	
	AE	EP 0 495 456	07-22-1992	Daikin Industries, Limited			
	AF	EP 0 882 797	12-09-1998	Unilever N.V. & Unilever PLC			
	AG	EP 0 965 578	12-22-1999	Suntory Limited			
	АН	EP 1 062 873	12-27-2000	N.V. Nutricia			
	Al	EP 1 252 824	10-30-2002	Abbott Laboratories		<u></u>	

		,,
Examiner	Date	
Signature	Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

PTO/SB/08B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
rk Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for for \$1449/PTO CO HIARBARD **Application Number** 10/576,239 INFORMATION DISCLOSURE **Filing Date** April 18, 2006 STATEMENT BY APPLICANT **First Named Inventor** Avidor SHULMAN Art Unit 1761 (Use as many sheets as necessary) **Examiner Name** Attorney Docket Number Sheet 2 of 5 7640-X06-058

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AJ	SUSAN E. CARLSON, PHD, et. al., Docosahexaenoic acid status of preterm infants at birth and following feeding with human milk or formula, Am. J. Clin. Nutri., 1986, pp. 798-804, v.44, American Society for Clinical Nutrition.	
	AK	VIRGILIO P. CARNIELLI, et. al., Feeding premature newborn infants palmitic acid in amounts and stereoisomeric position similar to that of human milk: effect on fat and mineral balance, Am. J. Clin. Nutr., 1995, pp. 1037-1042, v. 61, American Society for Clinical Nutrition.	
	AL	VIRGILIO P. CARNIELLI, et. al., Structural Position and Amount of Palmitic Acid in Infant Formulas: Effects on Fat, Fatty Acid, and Mineral Balance, Journal of Pediatric Gastroenterology and Nutrition, December 1996, pp. 553-560, v. 23, n. 5.	
	АМ	L. J. FILER, JR. et. al., Triglyceride Configuration and Fat Absorption by the Human Infant, J. Nutrition, 1969, pp. 293-298, v. 99.	
	AN	OLLE HERNELL, et. al., Digestion and Absorption of Human Milk Lipids, Perinatal Nutrition, 1988, pp. 259-272.	
	AO	SHEILA M. INNIS, et. al., Plasma and red blood cell fatty acids of low-birth-weight infants fed their mother's expressed breast milk or preterm-infant formula, Am. J. Clin. Nutr., 1990, pp. 994-1000, v. 51, American Society for Clinical Nutrition.	
	AP	SHEILA M. INNIS, et. al., Saturated fatty acid chain length and positional distribution in infant formula: effects on growth and plasma lipids and ketones in piglets, Am. J. Clin. Nutr., 1993, pp. 382-390, v. 57, American Society for Clinical Nutrition.	
	AQ	SHEILA M. INNIS, PHD et. al., Effects of Developmental Changes and Early Nutrition on Cholesterol Metabolism in Infancy: A Review, Journal of the American College of Nutrition, 1992, pp. 63S-68S, v. 11, n. 2.	
	AR	B. KOLETZKO, et. al., Effects of dietary long-chain polyunsaturated fatty acids on the essential fatty acid status of premature infants, European Journal of Pediatrics, 1989, pp.669-675, v. 148.	
F0 0	AS	ERIC L. LIEN, et. al., The Effect of Triglyceride Positional Distribution on Fatty Acid Absorption in Rats, Journal of Pediatric Gastroenterology and Nutrition, August 1997, pp. 167-174, v. 25, n. 2.	

Examiner	Date	
Signature	Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08B (09-06) Approved for use through 03/31/2007. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

133				e required to respond to a collection	of information unless it contains a valid OMB control number. Complete if Known
Substitu	ite for form 1449/PTO	18	E THE BURNEY OF	Application Number	10/576,239
INF	ORMATION	DIS	CLOSURE	Filing Date	April 18, 2006
(Use as many sheets as necessary)				First Named Inventor	Avidor SHULMAN
				Art Unit	1761
				Examiner Name	
Sheet	3	of	5	Attorney Docket Number	7640-X06-058

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	АТ	A. LOPEZ-LOPEZ, et. al., The influence of dietary palmitic acid triacylglyceride position on the fatty acid, calcium and magnesium contents of at term newborn faeces, Early Human Development, 2001, pp. S83-S94, v. 65 suppl.	
	AU	A. LUCAS, et. al., Randomised controlled trial of a synthetic triglyceride milk formula for preterm infants, Archives of Disease in Childhood, 1997, pp. F178-F184, v. 77.	
	AV	STEVEN E. NELSON, et. al., Absorption of Fat and Calcium by Infants Fed a Milk-Based Formula Containing Palm Olein, Journal of the American College of Nutrition, 1998, pp. 327-332, v. 17, n. 4.	
	AW	STEVEN E. NELSON, et. al., Palm olein in infant formula: absorption of fat and minerals by normal infants, American Journal Clinical Nutrition, 1996, pp. 291-296, v. 64.	
	AX	KARIN M. OSTROM, et. al., Lower Calcium Absorption in Infants fed Casein Hydrolysate- and Soy Protein-Based Infant Formulas Containing Palm Olein Versus Formulas without Palm Olein, Journal of the American College of Nutrition, 2002, pp. 564-569, v.21, n. 6.	
	AY	JANE C. PUTNAM, et. al., The effect of variations in dietary fatty acid on the fatty acid composition of erythrocyte phosphatidylcholine and phosphatidylethanolamine in human infants, The American Journal of Clinical Nutrition, July 1982, pp. 106-114, v. 36.	
	AZ	P. T. QUINLAN, et. al., The Relationship between Stool Hardness and Stool Composition in Breast- and Formula- fed Infants, Journal of Pediatric Gastroenterology and Nutrition, 1995, pp. 81-90, v. 20.	
	ВА	DONALD M. SMALL, The Effects of Glyceride Structure on Absorption and Metabolism, Annual Review Nutrition, 1991, pp. 413-434, v. 11.	
	ВВ	J. P. VAN BIERVLIET, et. al., Plasma apoprotein and lipd patterns in newborns: Influence of Nutritional factors, Acta. Paediatr. Scand., 1981, pp. 851-856, v.70.	
	вс	CHI-SUN WANG, et. al., Studies on the Substrate Specificity of Purified Human Milk Bile Saltactivated Lipase, J. of Biological Chemistry, 10 August 1983, pp. 9197-9202, v. 258, n. 15.	

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitution formation PTO				Complete if Known				
Substrau	on the same			Application Number	10/576,239			
INF	ORMATION	DIS	CLOSURE	Filing Date	April 18, 2006			
STATEMENT BY APPLICANT				First Named Inventor	Avidor SHULMAN			
				Art Unit	1761			
	(Use as many she	ets as n	iecessary)	Examiner Name				
Sheet	4	of	5	Attorney Docket Number	7640-X06-058			

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	BD	ELSIE M. WIDDOWSON, et. al., Body Gat of British and Dutch Infants, British Medical Journal, 22 March 1975, pp. 653-655, v. 1.	
	BE	Database Medline Online, USNLM, 15 November 1997, Cadogan J. et. al.L "Milk intake and bone mineral acquisition in adolescent girls: randomised, controlled intervention trial.", XP002315046, database access no. NLM9390050.	
	BF	Database Medline Online, USNLM, October 2003, Volek Jeff S. et. al.: "Increasing fluid milk favorable affects bone mineral density responses to resistance training in adolescent boys.", XP002315047, database access no. NLM14520257".	
	BG	Database Embase Online, Elsevier Science Pub., 2000, Gueguen L: "Calcium balance: Requirements, intake and bioavailability", XP002315048, database access no. EMB-2000369954.	
	вн	Database Embase Online, Elsevier Science Pub., 1 September 2003, Scholz-Ahrens K.E.: "Nutrients of milk and their relevance for health", XP002315049, Database access no. EMB-2003380690.	
	ВІ	Database FSTA Online, IFIS, 1996, Anonymous: "Betapol, a breakthrough in infant formula fats." XP002315600, Database access no. 96-1-08-N0030.	
	BJ	Enzymotec launches InFat - perfect fat for infant formulas, Online, 4 July 2003, XP002315599, Retrieved from Internet URL: www.foodingredientsfirst.com/newsmaker.	
	вк	Database Biosis Online, Biosciences Info. Service, 1996, Carnielli Virgilio P., et. al.: "Structural position and amount of palmitic acid in infant formulas: Effects on fat, fatty acid, and mineral balance", XP002315050, Database access no. PREV199799383168.	
	BL	Database FSTA Online, IFIS, 1999, Kennedy K. et. al: "Double-blind, randomized trial of a synthetic triacylglycerol in formula-fed term infants: effects on stool biochemistry, stool characteristics, and bone minealization.", XP002315051, Database access no. 2000-00-g0249.	
	ВМ	Database Embase Online, Elsevier Science Pub., 1979, Jenness R: "The composition of Human Milk", XP002315052, Database access no. EMB-1979225226.	

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

01	PE	
DEC	1 5 2006	
	U.S. Pasent	Appr and Trader

PTO/SB/08B (09-06)
Approved for use through 03/31/2007. OMB 0651-0031
Sept and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT				e required to respond to a collection	of information unless it contains a valid OMB control number. Complete if Known
				Application Number	10/576,239
				Filing Date	April 18, 2006
				First Named Inventor	Avidor SHULMAN
	// lee or many ch	ante as n	occessor)	Art Unit	1761
(Use as many sheets as necessary)				Examiner Name	1
Sheet	5	of	5	Attorney Docket Number	7640-X06-058

		NON PATENT LITERATURE DOCUMENTS	- <u>-</u>
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	BN	Database Medline Online, USNLM, Nov. 1997, Lucas A. et. al.: "Randomised controlled trial of a synthetic triglyceride milk formula for preterm infants.", XP002315783, access no. NLM9462186 & Archives of Disease in Childhood, Nov. 1997, Vol. 77, no. 3, pp F178-F184.	
	во	R. JACOBSON, et. al., Effect of short-term high dietary calcium intake on 24-h energy expenditure, fat oxidation, and fecal fat excretion, International Journal of Obesity. 2005, pp. 292-301, v. 29.	
	BP	ROBERT G. JENSEN, The composition of Bovine Milk Lipids: January 1995 to December 2000, J. Dairy Sci., American Dairy Science Association, 2002, pp. 295-350, v. 85.	
V	BQ	University of Maryland Med. Ctr. Web Site: http://www.umm.edu/home>medicalreference>alternative/complementarymedicine>tableofcontents>depletions>AntacidsAluminumCalciumandMagnesiumContainingPreparationscl.htm	

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.